UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,791	04/27/2001	Chihiro Uematsu		7893

24956 7590 10/25/2002

MATTINGLY, STANGER & MALUR, P.C.
1800 DIAGONAL ROAD
SUITE 370
ALEXANDRIA, VA 22314

EXAMINER	
TAYLOR, JANELL E	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 10/25/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/842,791	Applicant(s) UEMATSU ET AL.	
	Examiner Janell Cleveland Taylor	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *1-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Actions* .

DETAILED ACTION

Claim Objections

1. Claims 17-22 are objected to because of the following informalities: the claims are replete with minor grammatical errors. For example: the word "the" should precede "same" in the claims. Also, in claim 17 the word "first" appears after "second" in line 10 of the claim. In claim 21, the claim should read "which *have* different sequences", not "has". Also in claim 21, the word "and" should appear before the word "amplifying". This is not a comprehensive list of examples, but intended to show that the claims have multiple grammatical errors. Appropriate correction is required.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 17-22 are rejected under the judicially created doctrine of double patenting over claims 1-4 of U. S. Patent No. 6,225,064 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a method for amplifying nucleic acid comprising preparing primers with different sequences, having modules thereon, and amplifying the target.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 17-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Matsuzaki et al. (USPN 6,333,179).

Matsuzaki teaches methods and compositions for multiplex amplification of nucleic acids. In referring to the background of the invention and the prior art which existed at that time, Matsuzaki states "The yield of longer amplicons is often less than

the yield of shorter amplicons because of those differences in PCR amplification efficiency. Fig. 1 shows the difference in yields that one might expect, for example, when starting with equal primer concentration used it amplify amplicons of varying lengths: A, B, and C. There is a continuing need in the art for methods which permit the amplification of different sequences with the same efficiency so that approximately equimolar products result." (Background of Invention.) Matsuzaki goes on to state that an object of the present invention is to provide a method of performing multiplex PCR which achieve approximately equimolar products, or in other words, have the same reaction efficiency. In Table 1, in column 4 of Matsuzaki, there are two primers taught, SEQ ID NO: 1 and SEQ ID NO: 2, among others. These two primers fulfill the requirements of claims 17-22. They have a first sequence with a first module (SEQ ID NO: 1) and a second sequence with a second module (SEQ ID NO: 2). The first sequence is different than the second sequence of nucleotides, and the reaction efficiency is the same. (Col. 4, first paragraph). Furthermore, the primers have the same melting temperature (Col. 3, lines 55-60). They also have modules with the same composition, if you consider the first nucleotide of both primers to be a "module". (They both have the nucleotide 'T' in the first position). And since the claims do not define the length of the module, then a single nucleotide module anticipates the claims. Therefore, all of the claims are anticipated by Matsuzaki.

Summary

Claims 17-22 are objected to because of informalities. Claims 17-22 are rejected under the judicially created doctrine of double patenting. Claims 17-22 are rejected under 35

U.S.C. 102(e) as being anticipated by Matsuzaki et al. No claims are free of the prior art and no claims are allowable.

Conclusion

Any inquiries of a general nature relating to this application, including information on IDS forms, status requests, sequence listings, etc. should be directed to the Patent Analyst, Chantae Dessau, whose telephone number is (703) 605-1237.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janell Taylor Cleveland, whose telephone number is (703) 305-0273.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (703) 308-1152.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1634 via the PTO Fax Center using (703) 872-9306 or 872-9307 (after final). The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989.)

Janell Taylor Cleveland

September 11, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600